WYETH-AYERST RESEARCH

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Division of American Home Products Corporation

WORLDWIDE REGULATORY AFFAIRS

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September 29, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 00D-1350 "Draft Guidance for Industry on Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients"

Dear Sir or Madam:

Reference is made to the July 10, 2000 Federal Register Notice (65 FR 42387) which announced the availability of the Draft Guidance for industry entitled "Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients."

Wyeth-Ayerst Laboratories, a Division of American Home Products Corporation, appreciates the opportunity to provide comments on the Draft Guidance for industry. Wyeth-Ayerst is a major research-oriented pharmaceutical company with leading products in the areas of Women's Healthcare, cardiovascular and metabolic disease therapies, central nervous system drugs, infectious disease and anti-inflammatory agents, vaccines, and generic pharmaceuticals. American Home Products Corporation is one of the world's largest research-based pharmaceutical companies, and is a leading developer, manufacturer and marketer of prescription drugs and over-the-counter medications.

The purpose of this correspondence is to provide the Agency with Wyeth-Ayerst comments to the Draft Guidance for Industry on Combined Oral Contraceptives. These comments, which are provided in Attachment 1 to this letter, pertain only to the labeling that would be implemented for all combined oral contraceptives (i.e., class labeling) and does not concern labeling information Wyeth-Ayerst considers to be specific for its products subject to guidance.

Wyeth-Ayerst comments are presented in the order found in the Draft Guidance. For the Agency's convenience, Attachment 2 contains a copy of the Draft Guidance and is line-numbered to assist in cross-referencing provided comments. Attachment 3 to this letter includes a copy of the 1994 Labeling Guidance for Combined Oral Contraceptives (COCs) which is referenced throughout Wyeth-Ayerst's comments to the Draft Guidance.

Wyeth-Ayerst's formatting of its comments to the Draft Guidance begins with the specific Draft Guidance text, identified by line numbers. The respective Wyeth-Ayerst comments and/or rationale for revisions are listed immediately below along with literature references (Appendices 1-28), where appropriate. Wyeth-Ayerst's proposed revisions to the Draft Guidance text are

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provided following the rationale given for the change. A strike-through denotes a suggested Wyeth-Ayerst deletion while an underline denotes a suggested Wyeth-Ayerst addition.

Please contact Joyce Schwenk at (610) 902-3753, or the undersigned at (610) 902-3772 if there are any questions regarding the contents of this submission.

Sincerely,

WYETH-AYERST LABORATORIES

Jennifer W. Phillips, Pharm.D.
Director, Women's Healthcare
Worldwide Regulatory Affairs

cc: Dr. Susan Allen, Director, DRUDP

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